UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. GUIDANT LLC, formerly doing business as GUIDANT CORPORATION, Defendant.	Criminal No. 10-mj-67 DWF **INFORMATION** (21 U.S.C. § 331) (21 U.S.C. § 333) (21 U.S.C. § 334) (21 U.S.C. § 360i) (21 U.S.C. § 853(p)) (28 U.S.C. § 2461(c))

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this Information:

Introduction and General Allegations

1. Guidant Corporation was a business corporation organized under the laws of the State of Indiana with its principal place of business in Indianapolis, Indiana. Guidant, through the operation of several subsidiaries and affiliated corporations, including Cardiac Pacemakers, Inc. and Guidant Sales Corporation, engaged in the development, manufacture, processing, packaging, sale, marketing, and interstate distribution of medical devices in a broad range of medical specialties, including cardiac electrophysiology.

2. Boston Scientific Corporation ("Boston Scientific") acquired Guidant Corporation on or about April 21, 2006, at which time Guidant Corporation became

a wholly-owned subsidiary of Boston Scientific. On or about February 19, 2010, Guidant Corporation became a limited liability company organized under the laws of Indiana and was renamed "Guidant LLC" (hereinafter, "Guidant" or "the defendant").

3. Beginning in or about 1994 and through the time of its acquisition by Boston Scientific, Guidant engaged in the development, manufacture, processing, packaging, sale, marketing, and interstate distribution of implantable cardioverter-defibrillators ("ICDs"). ICDs are used to detect and treat abnormally fast heart rhythms that could result in sudden cardiac death. A specialized type of ICD used in the treatment of heart failure is known as a cardiac resynchronization therapy-defibrillator, or "CRT-D."

4. At all times relevant to this Information, Guidant's ICD and CRT-D business operations were conducted principally in Arden Hills, Minnesota.

5. The Federal Food, Drug, and Cosmetic Act ("FDCA"), among other things, governed the manufacture and interstate distribution of medical devices for human use, as codified at Title 21, United States Code, Section 301 *et seq.*

6. The FDCA required that manufacturers submit certain reports, notifications, and applications to the United States Food and Drug Administration ("FDA") with regard to medical devices. 21 U.S.C. § 360i. Among other things, a manufacturer of a medical device must promptly report any correction of a medical device if the correction was undertaken to reduce a risk to health posed by the

device. 21 U.S.C. § 360i(g). The failure or refusal to make such notification is prohibited. 21 U.S.C. § 331(q)(1).

7. The FDCA also prohibited the submission of any required report relating to a medical device that was false or misleading in any material respect. 21 U.S.C. § 331(q)(2).

The Medical Devices at Issue

8. ICDs and CRT-Ds treat, among other things, conditions in the human heart that can cause sudden cardiac death. ICDs and CRT-Ds prevent sudden cardiac death by constantly monitoring the electrical activity in a patient's heart for potentially lethal rhythms such as ventricular tachycardia and ventricular fibrillation. Upon detecting such dangerous rhythms, the ICD or CRT-D delivers an electrical shock to the heart in an effort to return the heart to a normal rhythm. If these devices fail to operate properly when needed, the patient can die within just a few minutes.

9. Physicians prescribe and surgically implant ICDs and CRT-Ds for patients who are at risk for such deadly heart rhythms. The implanted ICD or CRT-D is powered by an internal battery and connected to the heart via wires, called "leads." The leads, which are a separate medical device, allow the ICD and CRT-D to monitor the heart and also conduct the current needed to shock the heart to convert a lethal rhythm into a normal one.

10. At the times relevant to this Information, Guidant manufactured, distributed, and sold an ICD marketed under the name Ventak Prizm 2 DR ("Prizm

2") and a CRT-D marketed under the names Contak Renewal 1 and Contak Renewal 2 (collectively "Renewal"). The Contak Renewal 2, a version of the device marketed in some countries outside the United States, shared the same design as Contak Renewal 1.

11. An ICD or CRT-D can malfunction by failing to deliver the therapeutic amount of electricity to the heart because the electricity is diverted to some other conductor, such as the device itself, creating a short-circuit. The short-circuiting can occur across a gap, creating an electrical arc or "arcing."

12. Such arcing can allow a patient, whose heart could otherwise have been successfully treated by a working device, to die suddenly from cardiac arrest.

FDA Approval and Regulatory Action

13. The FDA is the agency of the United States government responsible for protecting the health and safety of the American public by assuring, among other things, that medical devices intended for use in the treatment of human beings are safe and effective for their intended uses. Pursuant to its statutory mandate, FDA regulated the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices.

14. Under the FDCA and its regulations, all medical devices fall into one of three classes, based on their risk to the health, safety, or welfare of the patient. Class III devices include devices that are intended for use in supporting or sustaining life, are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury. These devices are subject

to the highest level of regulation in order to provide reasonable assurance of safety and effectiveness for their intended use. 21 U.S.C. § 360c. The Contak Renewal 1 and 2 and Ventak Prizm 2 DR were Class III medical devices within the meaning of the FDCA.

15. Under the FDCA and its regulations, Guidant was required to submit and obtain FDA approval of a premarket approval application ("PMA") before it could lawfully market these devices in the United States. To be approved, a PMA application must provide FDA with sufficient information to demonstrate that there is a reasonable assurance that the device is safe and effective under the conditions of use recommended in the proposed labeling. 21 U.S.C. § 360e.

16. FDA approved Guidant's Contak Renewal 1 CRT-D through a PMA on or about December 20, 2002. The Renewal was commonly called Renewal 1 and was designated by Guidant as model number H135.

17. The Ventak Prizm 2 was a later generation version of another model of ICD. In the case of a later generation version of a device, a manufacturer may obtain approval to market the device by submitting a Supplemental PMA ("SPMA") application, based on the approval of the predecessor device. Guidant's Prizm 2, which was designated by Guidant as model number 1861, was approved by FDA pursuant to an SPMA on or about August 4, 2000.

18. Once FDA approved the Prizm 2 and Renewal devices, neither could be lawfully modified in any manner that affected their safety or effectiveness, unless

and until Guidant submitted an SPMA regarding the change, and received approval from FDA to market the modified device. 21 C.F.R. § 814.39(a).

19. Only changes that did not affect the devices' safety or effectiveness could be made to the devices without prior FDA approval. Such changes are required to be reported to FDA in annual postapproval reports. 21 C.F.R. § 814.39(b).

20. The labeling for a device includes all written, printed, or graphic material that is on a device or on its container, or accompanies the device. *See* 21 U.S.C. § 321(m). Labeling generally includes anything distributed by or on behalf of the manufacturer that supplements or explains the uses or manner of use of the device, whether or not the material physically accompanies the product when distributed.

21. The FDCA and its implementing regulations required that Guidant submit a written report to FDA within ten days of initiating any "correction" of a device undertaken to reduce a risk to health posed by the device. 21 U.S.C. § 360i(g); 21 C.F.R. § 806.10.

22. "*Correction* means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." 21 C.F.R. § 806.2(d) (italics in original).

23. "*Risk to health* means (1) a reasonable probability that use of, or exposure to the product will cause serious adverse health consequences or death; or

(2) that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious health consequences is remote." 21 C.F.R. § 806.2(j) (italics in original).

Prizm 2 Short Circuiting

24. In or about February 2002, Guidant learned that a Prizm 2 device implanted in a patient had failed. Through routine investigation, Guidant determined that the device had arced within the "header" of the device. The header is a formed plastic cap that channels the wires emanating from the metallic pulse generator to a port where the wires are connected to conductor leads that are implanted in the heart. The current had arced from the "feedthrough wire," which is designed to carry the electrical charge from the pulse generator to the leads, to the metal "backfill tube" on the top of the pulse generator. Because of the arc, the device failed to deliver proper therapy to the patient.

25. Guidant concluded in early 2002 that the arcing problem in the Prizm 2 could render the device unable to provide life-saving therapy when needed.

26. On or about April 16, 2002 and again on November 14, 2002, Guidant changed the design of newly manufactured Prizm 2 devices to correct the arcing problem.

27. The April 16, 2002 and November 14, 2002 changes to the Prizm 2 were intended to affect the safety and efficacy of the device.

28. Any change to the device that affected the safety and efficacy of the device was required to be submitted to FDA for review and approval in an SPMA. Instead, on or about August 19, 2003, Guidant reported the November 2002

correction to the Prizm 2 design in an annual report to the FDA. In that report, Guidant falsely described the change as a "minor alteration[] to the device . . . which [did] not affect the safety and effectiveness of the device" and stated that "[d]evice performance [was] unaffected by this change and the devices continue[d] to meet physical and functional requirements."

29. In the August 19, 2003, annual report to FDA regarding the Prizm 2, Guidant omitted the fact that the change was designed to be a corrective action to a problem with the devices that Guidant had concluded could render the device unable to provide life-saving therapy when needed.

Renewal Short Circuiting

30. Between in or about late 2003 and early July 2004, Guidant learned of three arcing events involving Renewal 1 and 2 devices implanted in patients that were similar to what had been observed in the Prizm 2 devices.

31. On or about June 21, 2004, J.R., a patient in Spain implanted with a Renewal 1 device was examined by his treating physician and a computerized wireless communications link with his implanted device was established through a process called "interrogation." Interrogation permits physicians to analyze, program, and diagnose the device by holding a telemetry wand over the implant site. The wand is connected to a portable computer called a ZOOM Programmer, which communicates with the implanted device. Messages and instructions displayed on the computer screen during this process are part of the device's labeling.

32. The interrogation of J.R.'s device resulted in the computer screen displaying a bright yellow-colored warning screen which displayed the following message:

WARNING: A shorted condition on the shocking leads has been detected.

A LOW shocking lead impedance has been recorded. Please evaluate lead integrity.

Select "Reset Fault" to continue.

33. J.R.'s physician evaluated the lead integrity as the warning screen had directed. No problem was detected with the leads, and J.R. was sent home.

34. In fact, J.R.'s implanted Renewal 1 itself – not the leads – had short circuited, and it was this arcing underneath the header of the CRT-D that had generated the yellow warning screen. Neither J.R. nor his physician was aware that his device was no longer functional and would not provide lifesaving treatment when needed.

35. A week later, on or about June 29, 2004, J.R. suffered a cardiac arrest at home. His implanted Renewal 1, which neither he nor his physician knew had arced previously, arced again when attempting to deliver the life-saving therapy J.R. needed. The device continued to malfunction, and J.R. died.

36. On or about July 5, 2004, Guidant personnel in Arden Hills, Minnesota learned of J.R.'s death in Spain, marking the fourth Renewal arcing event of which Guidant became aware.

37. As Guidant personnel investigated the Renewal arcing problem, they concluded that arcing could render the device unable to provide life-saving therapy when needed, and on or about August 26, 2004, they ordered the factory to stop shipping uncorrected devices.

38. During their investigation, Guidant personnel further determined that the appearance of the yellow warning screen was directly connected to the arcing in the Renewal.

39. The yellow warning screen message was false and misleading in that it told practitioners that a shorted condition was detected "on the shocking leads" and directed them to evaluate the leads – rather than in the Renewal device itself, which was where the short circuit was actually occurring.

40. None of the other instructions or labeling for the Renewal devices notified physicians that the observed warning screen could be indicating a problem within the device itself.

41. On or about March 2, 2005, Guidant sent for overnight delivery, via commercial interstate carrier, a "Product Update" entitled "Shorted Shock Lead Warning Screen" to all physicians treating patients with Guidant CRM devices.

42. Guidant distributed the Product Update in an effort to mitigate the risk to health posed by the Renewal devices. At the time of the distribution of the Product Update Guidant was aware of 12 Renewal short-circuiting failures, including the death in Spain, but the Product Update mentioned none of them. The

Product Update also did not advise that the warning screen's appearance indicated that the device may not function as intended.

43. Under the FDCA and its regulations, Guidant's distribution of the Product Update on or about March 2, 2005, was a relabeling of the Renewal and thus was a correction undertaken to reduce a risk to health posed by the device.

44. Guidant was required to report this action to FDA in writing within ten working days of initiating it. 21 U.S.C. § 360i(g); 21 C.F.R. § 806.10. The report of correction was required to include, *inter alia*, "[a] description of the event(s) giving rise to the information reported" and "[a]ny illness or injuries that have occurred with use of the device." 21 C.F.R. § 806.10.

45. Guidant failed and refused to furnish this required report to FDA. In response to an FDA official asking about the purpose of the Product Update, on or about April 1, 2005, Guidant sent a letter to FDA stating that the Product Update was not a correction and that there were no new or increased risks to patient health due to device performance.

46. On or about June 17, 2005, after consulting with FDA, Guidant formally communicated to physicians and the public about the arcing problems with the Prizm 2 and Renewal 1 devices, including information regarding the connection between the Renewal arcing and the yellow warning screen.

COUNT ONE
Submission of False and Misleading Report to FDA

47. The allegations contained in paragraphs 1 through 46 are realleged and incorporated herein as if set forth in full.

48. On or about August 19, 2003, in the State and District of Minnesota and elsewhere, the defendant,

GUIDANT LLC,

did submit, and cause to be submitted, a periodic post-approval report regarding the Ventak Prizm 2 DR Model 1861 ICD, a Class III medical device, to the United States Food and Drug Administration as required by Title 21, United States Code, Section 360i and Title 21, Code of Federal Regulations, Section 814.84, and which was materially false and misleading in that it reported a change to the device made on or about November 13, 2002, as one which did not affect the safety, effectiveness, or performance of the device.

All in violation of Title 21, United States Code, Sections 331(q)(2), 360i, and 333(a)(1).

COUNT TWO
Failure and Refusal to Report Medical Device Correction

49. The allegations contained in paragraphs 1 through 46 are realleged and incorporated herein as if set forth in full.

50. On or about March 2, 2005, in the State and District of Minnesota and elsewhere, the defendant,

GUIDANT LLC,

did fail and refuse to furnish a notification and other material and information required by and under Title 21, United States Code, Section 360i, in that the defendant failed to submit a written report to FDA of a correction it made to the Contak Renewal 1 cardiac resynchronization therapy-defibrillator, a Class III medical device, to wit, a communication to physicians entitled "Product Update -- Shorted Shock Lead Warning Screen," which correction was undertaken by the defendant to reduce a risk to health posed by the device.

All in violation of Title 21, United States Code, Sections 331(q)(1)(B), 360i(g), and 333(a)(1).

NOTICE OF FORFEITURE

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

1. As a result of the violation of Title 21, United States Code, Sections 331(q)(1)(B), 360i(g), and 333(a)(1) as set forth in this Information, the defendant,

GUIDANT LLC,

shall forfeit to the United States of America pursuant to Title 21, United States Code, Section 334, any Contak Renewal 1 cardiac resynchronization therapy-defibrillator devices, Model Number H135, manufactured prior to June 17, 2005 to be implanted in patients in the United States.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

a. Cannot be located upon the exercise of due diligence;

b. Has been transferred or sold to, or deposited with, a third party;

c. Has been placed beyond the jurisdiction of the Court;

d. Has been substantially diminished in value; or

e. Has been commingled with other property which cannot be divided without difficulty,

it is the intent of the United States of America, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of $42,079,675 from defendant, that is, the value of the property subject to forfeiture.

All pursuant to Title 21, United States Code, Sections 334 and 853, and Title 28, United States Code, Section 2461(c).

Dated this 25th day of February, 2010.

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Acting under authority
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